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EXAMINER	
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ART UNIT	PAPER NUMBER
1637	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,975	DAVYDOVA ET AL.	
	Examiner	Art Unit	
	ANGELA BERTAGNA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *83-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-94* is/are rejected.

7)☒ Claim(s) *85* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Applicant's response filed on January 24, 2008 is acknowledged. Claims 83-94 are currently pending. In the response, Applicant canceled claims 54-82 and presented new claims 83-94.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. 10/153,219 and Provisional Application 60/292,845, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The '219 and '845 applications do not teach forming a transcription substrate by ligating two or more oligonucleotides to each other in a template-dependent process as required

by claims 83 and 94, and therefore, they fail to adequately support the subject matter of the instant claims 83-92 and 94. Also, the '219 and '845 applications do not teach that the target nucleic acid consists of a nucleic acid sequence tag joined to an analyte-binding substance and that the method further comprises forming a specific binding pair between an analyte and an analyte-binding agent prior to conducting step (b) in the method of claim 83, and therefore, they do not provide adequate support for the method of claims 88 and 92. Accordingly, claims 83-92 and 94 have only been granted benefit of Provisional Application 60/436,062, filed December 23, 2002. This date has been used for prior art purposes. Claim 93 does find adequate support in the prior-filed applications, and for this claim, an effective filing date of May 22, 2001 has been used for prior art purposes.

New Grounds of Rejection/Objection Necessitated by the Claim Amendments

Claim Objections

3. Claims 85 is objected to because of the following informalities:

(a) Claim 85 appears to contain a typographical error in step (b) where "on a said target nucleic acid" is recited. It would appear that "on said target nucleic acid" was intended. Appropriate correction is required.

Claim Rejections – 35 USC § 112, 1st paragraph (New Matter)

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 83-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Section 2163.03 I of the MPEP states, "An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. *In re Wright*, 866 F.2d 422, 9USPQ2d 1649 (Fed. Cir. 1989)."

Section 2163.06 I of the MPEP states, "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

The instant claims 83-92 are new claims presented after the cancellation of all of the previously pending claims. They are drawn to a method for making RNA via transcription of a DNA substrate with RNA polymerase. The method comprises obtaining a DNA substrate by ligating two or more oligonucleotides in a template-dependent process and transcribing the resulting ligation product with an RNA polymerase (see claim 83). Claim 83, from which claims 84-92 depend, does not recite that the RNA polymerase used to practice the method lacks helicase-like activity and can transcribe RNA using a single-stranded promoter. Thus, the newly filed claims are broader in scope than the previously considered claims. The limitation requiring the RNA polymerase to lack helicase-like activity and possess the ability to transcribe RNA from a single-stranded promoter was present in the originally filed claims and in the claim set filed on November 17, 2006. Based on the previously filed claims and the specification (see paragraphs

18, 37, 265, 266, 332, and 359-363), this limitation appears to be an essential or critical feature of the originally disclosed invention. As noted in MPEP 2163.05, "A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement. See Gentry Gallery, 134 F.3d at 1480, 45 USPQ2d at 1503; In re Sus, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962)." Accordingly, claims 83-92 have been rejected under 35 U.S.C. 112, first paragraph for introducing new matter.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 85-87, 91, 93, and 94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 85 is indefinite, because it recites the limitations "said first oligonucleotide" in step (b)(ii) and "said RNA polymerase" in steps (c) and (d). There is insufficient antecedent basis for these limitations in the claim. There is sufficient antecedent basis for "said first probe oligonucleotide" and "said N4 virion RNA polymerase".

Claims 86 and 87 are also indefinite, since they depend from claim 85.

Claim 87 is further indefinite, because the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 91, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 93 is indefinite, because it recites the limitations "said oligonucleotide" in lines 5, 7, & 8 and "said RNA polymerase" in line 7. There is insufficient antecedent basis for these limitations in the claim. There is sufficient antecedent basis for "said single-stranded DNA oliognucleotide" and "said N4 virion RNA polymerase".

Claim 94 is indefinite, because it depends from claim 93.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 83, 88, and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Dattagupta (EP 0 427 074 A2; cited on IDS).

These claims are drawn to a method for making RNA that comprises ligating two or more oligonucleotides in the presence of a target nucleic acid and transcribing the ligation product with an RNA polymerase.

Regarding claim 83, Dattagupta teaches a method for making RNA using a target nucleic acid in a target nucleic acid as a template comprising:

(a) amplifying the target nucleic acid sequence in a template-dependent process that comprises ligating two or more oligonucleotides in the presence of the target nucleic acid (see Figure 5 and page 8, lines 22-31)

(b) transcribing the ligation product from step (a) with an RNA polymerase (see Figure 5 and page 8, lines 32-34).

Regarding claims 88 and 92, Dattagupta teaches that the target nucleic acid consists of a target sequence tag that is joined to an analyte-binding substance, specifically a nucleic acid, and prior to performing step (b) in the method of claim 83, the method comprises (see page 7, lines 30-39):

(a) obtaining the analyte-binding substance to which the target sequence tag is joined

(b) contacting the analyte-binding substance to which the target sequence tag is joined with the analyte (the immobilized probe sequence) to form a specific binding pair

(c) removing the analyte-binding substance molecules that are not bound to the analyte from the specific binding pair

(d) providing the resulting specific binding pair.

8. Claim 83 is rejected under 35 U.S.C. 102(e) as being anticipated by Wenz et al. (US 2003/0119004 A1; cited previously).

Claim 83 is drawn to a method for making RNA that comprises ligating two or more oligonucleotides in the presence of a target nucleic acid and transcribing the ligation product with an RNA polymerase.

Regarding claim 83, Wenz teaches a method for making RNA using a target nucleic acid in a target nucleic acid as a template comprising:

(a) amplifying the target nucleic acid sequence in a template-dependent process that comprises ligating two or more oligonucleotides in the presence of the target nucleic acid (see Figures 5A-5B and paragraph 132)

(b) transcribing the ligation product from step (a) with an RNA polymerase (see Figure 5C and paragraph 132).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 84, 85, and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dattagupta (EP 0 427 074 A2; cited on IDS) in view of Dai et al. (Genes & Development (1998) 12: 2782-2790; cited on IDS).

Claims 84, 85, and 89 are drawn to the method of claim 83, wherein an N4 virion RNA polymerase is used to transcribe the ligated products produced by the method of claim 83.

Dattagupta teaches the method of claims 83, 88, and 92, as discussed above.

Regarding claim 85, Dattagupta teaches that the method of claim 83 comprises (see Figure 5, page 8, lines 22-34, and Example 4 at page 13, lines 25-51):

(a) obtaining an RNA polymerase

(b) obtaining DNA, wherein the obtaining comprises:

(i) providing a sample containing a target nucleic acid having a target nucleic acid

(ii) annealing first and second probe oligonucleotides adjacently to each other on the target nucleic acid, wherein the first oligonucleotide contains an RNA polymerase promoter sequence

(iii) ligating the first and second probe oligonucleotides to one another to generate the DNA

(c) admixing the RNA polymerase and the DNA

(d) culturing the RNA polymerase and the DNA, thereby generating RNA.

Dattagupta teaches using T7 RNA polymerase to conduct the method (see Example 4 on page 13) rather than an N4 virion RNA polymerase.

Regarding claims 84, 85, and 89, Dai teaches that the N4 virion RNA polymerase is capable of transcribing supercoiled double-stranded DNA substrates in the presence of *E. coli* single-strand binding protein (see abstract and pages 2783, 2788, and 2789).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to utilize an N4 virion RNA polymerase when practicing the method of Dattagupta. Since Dattagupta taught performing the transcription step using an RNA polymerase that recognized a double-stranded promoter (see Example 4, where T7 RNAP is taught), an ordinary artisan would have been motivated to use any RNA polymerase known to possess such activity to practice the method recognizing its suitability for the intended purpose. As noted in MPEP 2144.07, selection of a known material based on its suitability for the intended purpose is *prima facie* obvious in the absence of secondary considerations. Also, as noted in MPEP 2144.06, it is *prima facie* obvious to substitute art-recognized equivalents useful for the same purpose. In this case, as evidenced by the teachings of Dai cited above, the N4 virion RNA polymerase was known to be capable of transcribing RNA using a double-stranded promoter in the presence of *E. coli* single-stranded binding protein. Therefore, an ordinary practitioner of the method taught by Dattagupta would have been motivated to utilize this polymerase to practice the method with a reasonable expectation of success. Thus, the methods of claims 84, 85, and 89 are *prima facie* obvious over Dattagupta in view of Dai.

11. Claims 84-87 and 89-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dattagupta (EP 0 427 074 A2; cited on IDS) in view of Kazmierczak et al. (WO 02/095002 A2; newly cited).

The applied reference (Kazmierczak et al) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 84-87 and 89-91 are drawn to the method of claims 83 and 88, wherein an N4 virion RNA polymerase is used to practice the method.

Dattagupta teaches the method of claims 83, 88, and 92, as discussed above.

Regarding claim 85, Dattagupta teaches that the method of claim 83 comprises (see Figure 5, page 8, lines 22-34, and Example 4 at page 13, lines 25-51):

(a) obtaining an RNA polymerase

(b) obtaining a single-stranded DNA oligonucleotide containing an RNA polymerase promoter sequence, wherein the obtaining comprises:

(i) providing a sample containing a target nucleic acid having a target nucleic acid

(ii) annealing first and second probe oligonucleotides adjacently to each other on the target nucleic acid, wherein the first oligonucleotide contains an RNA polymerase promoter sequence

(iii) ligating the first and second probe oligonucleotides to one another to generate the DNA

(c) admixing the RNA polymerase and the DNA

(d) culturing the RNA polymerase and the DNA, thereby generating RNA.

Dattagupta teaches using T7 RNA polymerase to conduct the method (see Example 4 on page 13) rather than an N4 virion RNA polymerase.

Kazmierczak teaches a method for making RNA from a single-stranded DNA oligonucleotide containing an N4 virion RNA polymerase promoter that anticipates the method of claim 93, as discussed above.

Regarding claims 84, 85, and 89, the method of Kazmierczak comprises using mini-vRNAP or the Y678F variant of mini-vRNAP to transcribe a single-stranded DNA oligonucleotide containing an N4 RNA polymerase promoter sequence (see page 3, last paragraph – page 4, second paragraph, for example).

Regarding claims 86 and 90, Kazmierczak teaches that mini-vRNAP is a single transcriptionally active protein that is approximately 1,100 amino acids in length and that

corresponds to the middle 1/3 of the complete N4 virion RNA polymerase between amino acid 998 and amino acid 2103 of the full-length N4 virion RNA polymerase (page 69, paragraph 2).

Regarding claims 87 and 91, Kazmierczak teaches that the N4 virion RNA polymerase is a polypeptide having the amino acid sequence of SEQ ID NO: 4, SEQ ID NO; 6, or SEQ ID NO: 8 (see page 4, paragraph 2).

Kazmierczak teaches that most DNA-dependent RNA polymerases require a double-stranded transcription substrate, thereby limiting methods of RNA synthesis to those in which a double-stranded DNA transcription substrate is available (page 2, paragraph 2). Kazmierczak teaches that the above N4 virion RNA polymerase is capable of transcribing RNA from a single-stranded promoter, a denatured double-stranded promoter, or a double-stranded promoter (see page 2, paragraph 2, page 4, paragraph 1, and page 4, last paragraph – page 5, first paragraph).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to utilize an N4 virion RNA polymerase as taught by Kazmierczak when practicing the method of Dattagupta. An ordinary artisan would have been motivated to do so with a reasonable expectation of success, because Kazmierczak taught that the N4 virion RNA polymerase could transcribe single-stranded and double-stranded substrates (see page 2, paragraph 2, page 4, paragraph 1, and page 4, last paragraph – page 5, first paragraph). An ordinary artisan would have recognized from these teachings of Kazmierczak that utilizing the N4 virion RNA polymerase in the method of Dattagupta would have provided the advantage of increased flexibility regarding the DNA substrate to be transcribed. Thus, the methods of claims 84-87 and 89-91 are *prima facie* obvious over Dattagupta in view of Kazmierczak.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 83-94 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 108, 111, 112, 119, and 127 of copending Application No. 10/744,815.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 108 of the '815 application recite a species of the method generically claimed in the instant claim 83. Therefore, claim 108 of the '815 anticipates the instant claim 83. Also, claims 119 and 127 of the '815 recite a species of the method generically claimed in the instant claim 93. Therefore, claims 119 and 127 of the '815 application anticipate the instant claim 93. The limitations of the instant claims 84-87, 89-91, and 94 are recited in claims 108 and 127 of the '815 application. The limitations of the instant claim 88 are recited in claims 111 and

122 of the '815 application. The limitations of the instant claim 92 are recited in claims 112 and 123 of the'815 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

15. Applicant's arguments filed on January 24, 2008 regarding priority have been fully considered, but they were not persuasive. Applicant argues that the newly presented claims are fully supported by the prior filed applications (see pages 11-12). This argument was not found persuasive, because the cited passage in the '219 application does not clearly indicate that the template nucleic acid used in the transcription reaction is obtained by ligase chain reaction (LCR) amplification. As noted by Applicant, paragraphs 98 and 109 of the '219 application state that nucleic acids can be amplified via the ligation of oligonucleotides. However, there is no indication in these paragraphs or elsewhere that LCR-amplified or otherwise amplified nucleic acids are used as the substrate for RNA polymerase-mediated transcription. In the absence of this nexus between the claimed subject matter and the disclosure of the prior-filed applications, an ordinary artisan would not reasonably conclude that Applicant was in possession of the claimed invention, and therefore, benefit of the prior-filed application cannot be granted. Furthermore, as noted above, the '219 application does not provide adequate support for claims 88 and 92 where the target nucleic acid has a tag and an analyte binding agent attached thereto and the method further comprises providing the target nucleic acid together with an analyte bound to the analyte binding agent. Finally, the issue of priority is moot in view of the new art

applied above (Dattagupta), which predates Applicant's earliest possible effective filing date of May 22, 2001.

Applicant's arguments, see page 12, filed on January 24, 2008, with respect to the objection to the oath/declaration have been fully considered and are persuasive. Applicant's submission of a new oath/declaration obviates the objection, and therefore, it has been withdrawn.

Applicant's arguments, see page 13, filed on January 24, 2008, with respect to the objections to the abstract and the specification have been fully considered and are persuasive. Applicant's amendments to the specification and to the abstract obviate the objections, and therefore, they have been withdrawn.

Applicant's arguments regarding the rejection of claims 54-80 under 35 U.S.C. 112, second paragraph are moot in view of the cancellation of these claims.

Regarding the previously made rejections under 35 U.S.C. 103(a) citing Wenz et al. (US 2003/0119004 A1), Applicant first argues that the newly filed claims have an effective filing date of May 22, 2001, and therefore, Wenz does not qualify as prior art (see page 13). This argument was not found persuasive, because as discussed above, prior-filed Application Serial Nos. 10/153,219 and 60/292,845 do not provide adequate support for the claimed subject matter. As a result, the instant claims only obtain benefit of Provisional Application 60/436,062, which was filed on December 23, 2002. Therefore, the Wenz reference qualifies as prior art.

Applicant also argues that the Wenz reference does not teach all of the elements of claims 88-92 (see page 13). This argument is moot in view of the new grounds of rejection presented above.

Applicant's response does not appear to address the provisional obviousness-type double patenting rejection citing co-pending Application Serial No. 10/744,815. This rejection has been maintained in accordance with MPEP § 804.

Conclusion

16. No claims are currently allowable. It is noted that claims 93 and 94 are free of the art, but they have rejected for other reasons, specifically, failure to comply with the provisions of 35 U.S.C. 112, second paragraph and provisional obviousness-type double patenting.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tyagi et al. (US 5,759,773) teaches a method for making RNA comprising ligating two oligonucleotides hybridized to a template nucleic acid and transcribing the ligated product using RNA polymerase (see abstract, Figure 7, and Example 2 at column 19). Livache et al. (US 5,795,715) teaches a method for making RNA that comprises conducting a ligase chain reaction followed by transcription using RNA polymerase (see abstract and columns 3-4). Dahl (US 6,562,575 B1; cited on IDS) teaches a replicase-based method of identifying an analyte in a sample (see abstract and Figures 3 & 5).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

amb

/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637